Remarks

The specification is amended to address informalities such as typographical errors and patent numbers. For example, paragraph [0054] is amended to better track the language of originally filed paragraph [0066]. No new matter is presented.

The Office Action restricted this application into Groups I (claims 1-17, 26-29 and 39-44), and II (claims 18-25 and 30-38). The claims of Group II are herein cancelled without prejudice.

Claims 39-44 were rejected under 35 U.S.C. Section 112, first paragraph. Claims 1, 7, 8, 11, 26 and 39 – 43 were rejected under 35 U.S.C. § 102(b) as being anticipated by Gellman et al. U.S. Pat. No. 6,042,534. Claim 44 was rejected under 35 U.S.C. Section 103 (a) as being unpatentable over Gellman et al. U.S. Pat. No. 6,042,534. Claim 9 was rejected under 35 U.S.C. Section 103 (a) as being unpatentable over Gellman et al. U.S. Pat. No. 6,042,534 in view of U.S. Pat. No. 4,403,604 to Wilkinson. Claims 2-6, 10-17 and 27-29 were indicated as being allowable, if rewritten. This appears to be a typographical error insofar as claim 11 was rejected based on Gellman. Thus, applicants proceed from the assumption that claims 2-6, 10 and 12-17 and 27-29 were allowable, if rewritten.

Applicants respectfully disagree with the rejection based on 35 U.S.C. Section 112, first paragraph. The specification is replete with examples and description of the invention claimed in claims 39-44. For example (not intended to be limiting), Fig. 7B shows a substantially elliptical pattern 702A in the presence of tension on the sling. In the absence of tension (Fig. 7A) the pattern is a square. Thus, the elliptical pattern 702A is absent from the sling when the sling is free of tension.

With respect to the rejection of claims 39-44 based on Gellman et al., reference character 20 of Gellman discloses a visual indicator 20. The visual indicator 20 enables the surgeon to position the sling relative to the urethra so that the urethra generally extends across the center of the sling. See column 9, lines 59-61. In contrast, claim 39 calls for "visual indicia present on said mesh corresponding to the presence of a predetermined tension in said sling." There is no indication that the centering visual indicia 20 of Gellman would meet the express limitation of claim 39.

The Office Action also referenced holes 18 as possibly meeting the elements of claim 42. However, reference characters 18 are suture receiving sites. The undersigned attorney believes that the presence of a suture within the suture receiving site would make it extremely difficult (if not impossible) to view the shape of the suture receiving site. Thus, it would also make it difficult to compare the shape of the site with a reference shape in order to determine tension on the sling. As a result, it is respectfully submitted that this feature of Gellman does not render the invention of claims 39-44 unpatentable.

As a result, it is respectfully submitted that the rejections of claims 39-44 should be withdrawn.

This amendment is believed to render the rejection of claims 1, 7, 8, 11, and 26 moot. The rejected claims are herein cancelled without prejudice in order to expedite prosecution of the present case.

Claim 10 was indicated as being allowable. Claim 10 has been substantially rewritten. Applicants respectfully submit that claim 10 defines allowable subject matter and respectfully request a fresh reconsideration.

The Examiner is respectfully thanked for granting an interview to the undersigned attorney on Tuesday, March 25 at 1:00 p.m. At the interview, _____

_____

Claims 2, 7-9, 11, 18-25 and 30-38 have been cancelled. Claims 45-47 are added herein. No new matter is presented.

The dependent claims each add additional features to their respective independent claims. The independent claims are patentable for the reasons given above. Thus, the dependent claims are likewise patentable.

A supplemental information disclosure statement was mailed in this case on March 14, 2003. Consideration of that supplemental information disclosure statement is also herein requested.

In view of the above, it is submitted that the application is in condition for allowance. Reconsideration of the application is requested.

Five independent claims (net) are added by this amendment. Please charge the fee for the submission of these five additional independent claims to Deposit Account No. 501921. Please charge any fees required for the submission of this amendment and the supplemental

information disclosure statement to Deposit Account No. 501921, including the cost for any extension of time. Should such an extension of time be necessary, please consider this document a petition for such an extension.

Respectfully submitted,

Registration Number	Telephone Number
34,109	952-930-6135
Date	
March __, 2003	

By _____
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Patent Application
Attorney Docket No: 687-401

Version With Markings to Show Changes Made

Please replace paragraph [0032 with]:

[0032] In a preferred embodiment, a synthetic filamentous material suitable for fabricating a mesh for use as a sling include a commercially available material comprised of a Rashel knit mesh made from 150 denier polyester yarn. Such a mesh has a hole size of approximately 1/32" (0.794 mm) and a weight of approximately 4.7 oz/yd. (133.25 gr/.914 m). The yarn is a multi-filament yarn. In another embodiment a mesh known as Mersilene™ may be used.

Please replace paragraph [0054] with:

[0054] Depending upon the parameters of the coating process used, varying degrees of silicone thickness surrounding the mesh yarns can be obtained. However, in preferred embodiments [all circumstances], the holes or pores 24 remain open after coating. Referring to Figures 2A, 2B, 3A and 3B, depending upon the desire or need of the user, a sling can be coated so as to comprise a coated mesh material having a thickness ranging from about .024 inches (0.61 mm) to about .036 inches (0.914 mm) (Figures 3A, 3B) or from about .020 inches (0.508 mm) to about .025 inches (0.635 mm) (Figures 2A and 2B). In one embodiment, the thickness of the sling material in the uncoated state is about .020 inches (0.508 mm) plus or minus about 0.002 inches. In a preferred embodiment, the size of the holes or pores 24 after coating is preferably in the range of about .040 inches (1.016 mm) to about .055 inches (1.397 mm).

Please replace paragraph [0056] with:

[0056] It is contemplated that the present invention can be used with a variety of sling systems and methods for treating urinary incontinence. For example, a coated sling in accordance with the present invention, can be used with the system for the long term cure of recurrent urinary female incontinence as described in co-pending

U.S. Patent [application Serial] No. 6,328,686, [09/236,212 filed January 1, 1999 (Kovac), entitled "System and Method for Treating Female Urinary Incontinence," the entire disclosure of which is hereby incorporated by reference. When used in such a system, a silicone-coated sling can be installed in vivo using the vaginal installation procedure as described in the application. Alternatively, a coated sling in accordance with the present invention can be prefabricated according to the dimensions and shapes as described, for example, in U.S. Patent No. 6,042,534 issued March 28, 2000 entitled "Stabilization sling for use in minimally invasive pelvic surgery" and installed as described in U.S. Patent No. 6,042,534. A coated sling of the present invention can also be installed abdominally or laparoscopically using procedures well known in the art.

Please replace paragraph [0071] with:

[0071] After removing the material from the hoops, the silicone coated mesh material can then be fabricated as desired into a sling for use in treating urinary incontinence. As described previously, a silicone coated mesh material of the present invention, can be used to fabricate a sling such as described in [co-pending] U.S. Patent [Application Serial] No. 6,328,686, [09/236,212, filed January 1, 1999] and then surgically implanted into a patient suffering from urinary incontinence.

Please replace paragraph [0078] with:

[0078] The invention as disclosed in the embodiment of Figures 7A and 7B is not limited to visual indicia in the form of geometrical patterns. For example, the visual indicia could be a series of seemingly random lines that, under the target tension, become al[l]igned into a straight line or into a geometrical pattern such as a triangle. As another example, the visual indicia could be a collection of marks or characters that, under the target tension, become al[l]igned to spell a word such as "OK," or "STOP," or "LIMIT." In one embodiment the word could [even] spell the manufacturer of the sling, such as "AMS."

Patent Application
Attorney Docket No: 687-401

Version With Markings to Show Changes Made to Claims

In the Claims:

1. (Amended) A sling for insertion into a patient comprising:

a surgical sling adapted to support the urethra in its normal anatomic position and to prevent abnormal urethral descent under intraabdominal pressure;

said surgical sling comprising a length of material having a longitudinal axis, and a latitudinal axis;

wherein said material has a first elongation property along said longitudinal axis, and a second elongation property along said latitudinal axis[.],

said first and second elongation property being different from each other, and

wherein said second elongation property is greater than said first elongation property.

Please cancel claim 2.

3. (Amended) [The] A sling [as set forth in claim 1,] for insertion into a patient comprising:

a surgical sling adapted to support the urethra in its normal anatomic position and to prevent abnormal urethral descent under intraabdominal pressure;

said surgical sling comprising a length of material having a longitudinal axis, and a latitudinal axis;

wherein said material has a first elongation property along said longitudinal axis, and a second elongation property along said latitudinal axis,

said first and second elongation property being different from each other, and

wherein said first elongation property is approximately 8% elongation beyond a normal state of said sling material when said sling material is subjected to a tension of approximately 5 lbs.

5. (Amended) [The] A sling [as set forth in claim 1,] for insertion into a patient comprising:

a surgical sling adapted to support the urethra in its normal anatomic position and to prevent abnormal urethral descent under intraabdominal pressure;

said surgical sling comprising a length of material having a longitudinal axis, and a latitudinal axis;

wherein said material has a first elongation property along said longitudinal axis, and a second elongation property along said latitudinal axis,

said first and second elongation property being different from each other, and

wherein said first elongation property is in the range of approximately 24%-28% elongation beyond a normal state of said sling material when said sling is subjected to a tension of approximately 20 lbs.

Please cancel claims 7-9 without prejudice.

10. (Amended) [The] A sling [as set forth in claim 9,] for insertion into a patient comprising:

a surgical sling adapted to be implanted in a tension free rest position to support the urethra;

said surgical sling material comprising a length of polypropylene material having pores for promoting tissue ingrowth, a pair of major surfaces, a pair of ends and a pair of edges, and a longitudinal axis;

wherein said polypropylene material has a central region with at least one major surface coated with silicone, the silicone coated central region being adapted to be placed adjacent the urethra to avoid tissue erosion, and end regions without silicone coating; and

wherein said silicone coated [mesh] polypropylene in the central region has a thickness within the range of approximately .024" (0.61 mm) to .036" (0.914 mm).

Please cancel claim 11 without prejudice.

12. (Amended) [The] A sling [as set forth in claim 7,] for insertion into a patient comprising:

a surgical sling adapted to support the urethra in its normal anatomic position and to prevent abnormal urethral descent under intraabdominal pressure;

said surgical sling comprising a length of material having a longitudinal axis, and a latitudinal axis;

wherein said material has a first elongation property along said longitudinal axis, and a second elongation property along said latitudinal axis,

said first and second elongation property being different from each other,

said material is coated with a substance that enhances biocompatibility, and

wherein said first elongation property is in the range of approximately 19.5-21.5% elongation beyond a normal state of said sling material when said sling material is subject to a tension of approximately 20 lbs.

14. (Amended) [The] A sling [as set forth in claim 7,] for insertion into a patient comprising:

a surgical sling adapted to support the urethra in its normal anatomic position and to prevent abnormal urethral descent under intraabdominal pressure;

said surgical sling comprising a length of material having a longitudinal axis, and a latitudinal axis;

wherein said material has a first elongation property along said longitudinal axis, and a second elongation property along said latitudinal axis,

said first and second elongation property being different from each other,

said material is coated with a substance that enhances biocompatibility, and

wherein said first elongation property is approximately 2.5% elongation beyond a normal state of said sling material when said sling material is subject to a tension of approximately 5 lbs.

15. (Amended) [The] A sling [as set forth in claim 7,] for insertion into a patient comprising:

a surgical sling adapted to support the urethra in its normal anatomic position and to prevent abnormal urethral descent under intraabdominal pressure;

said surgical sling comprising a length of material having a longitudinal axis, and a latitudinal axis;

wherein said material has a first elongation property along said longitudinal axis, and a second elongation property along said latitudinal axis,

said first and second elongation property being different from each other,

said material is coated with a substance that enhances biocompatibility, and

wherein said second elongation property is approximately 65% elongation beyond a normal state of said sling material when said sling material is subject to a tension of approximately 5 lbs.

16. (Amended) [The] A sling [as set forth in claim 7,] for insertion into a patient comprising:

a surgical sling adapted to support the urethra in its normal anatomic position and to prevent abnormal urethral descent under intraabdominal pressure;

said surgical sling comprising a length of material having a longitudinal axis, and a latitudinal axis;

wherein said material has a first elongation property along said longitudinal axis, and a second elongation property along said latitudinal axis,

said first and second elongation property being different from each other,

said material is coated with a substance that enhances biocompatibility, and

wherein said first elongation property is approximately 10.5% elongation beyond a normal state of said sling material when said sling material is subject to a tension of approximately 5 lbs.

17. (Amended) [The] A sling [as set forth in claim 7,] for insertion into a patient comprising:

a surgical sling adapted to support the urethra in its normal anatomic position and to prevent abnormal urethral descent under intraabdominal pressure;

said surgical sling comprising a length of material having a longitudinal axis, and a latitudinal axis;

wherein said material has a first elongation property along said longitudinal axis, and a second elongation property along said latitudinal axis,

said first and second elongation property being different from each other,

said material is coated with a substance that enhances biocompatibility, and

wherein said second elongation property is approximately 25% elongation beyond a normal state of said sling material when said sling material is subject to a tension of approximately 5 lbs.

Please cancel claim 26 without prejudice.

27. (Amended) A sling [as set forth in claim 26,] for insertion into a patient comprising:

a surgical sling adapted to support the urethra in its normal anatomic position and to prevent abnormal urethral descent under intraabdominal pressure;

said surgical sling comprising a length of material having a longitudinal axis, and a latitudinal axis;

wherein said sling comprises a plurality of regions along its longitudinal axis and wherein each region contains differing elongation properties from an immediately adjacent region, and

wherein said sling material has a coated central region having an increased longitudinal elongation property and a somewhat decreased latitudinal elongation property as compared to elongation properties of said central region in a normal state.

45. (Added) A sling according to claim 10 wherein the pores of the polypropylene material in the central region remain open and clear of silicone.

46. (Added) A sling according to claim 10 wherein said polypropylene comprises non-knitted polypropylene fibers.

47. (Added) A sling according to claim 46 wherein said non-knitted polypropylene fibers are multidirectional.